FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2251–2300

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., *May 26, 1948.*

CONTENTS *

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2251. Misbranding of sulfathiazole tablets, thyroid tablets, seconal pulvules, and nembutal capsules. U. S. v. Carl P. Fletcher. Plea of guilty. Fine, $200. (F. D. C. No. 21456. Sample Nos. 40445–H to 40447–H, incl., 40453–H.)

INFORMATION FILED: March 31, 1947, Eastern District of Missouri, against Carl P. Fletcher, manager of the Ellis Drug Store, Clayton, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of April 11, 1945, and January 20, 1946, from Indianapolis, Ind., New York, N. Y., and Chicago, Ill., to St. Louis, Mo., of quantities of *sulfathiazole tablets, thyroid tablets, seconal pulvules, and nembutal capsules.*

LABEL, WHEN SHIPPED: "Tablets Sulfathiazole * * * 0.5 Gm. (7.72 grs.) * * * Eli Lilly & Company Indianapolis," "Pulvules Seconal Sodium 1½ grs. (0.1 Gm.) * * * Eli Lilly and Company Indianapolis," "1 Gr. Thyroid Tablets U. S. P. * * * Supreme Pharmaceutical Co. Distributors New York City, N. Y.," or "Capsules Nembutal (Pentobarbital Sodium, Abbott) * * * 1½ Grs. * * * Abbott Laboratories North Chicago, Ill."

* For presence of a habit-forming narcotic without warning statement, see No. 2251; failure to comply with the packaging requirements of an official compendium, No. 2273; deceptive packaging, No. 2284.

ALLEGED VIOLATION: On or about July 19, 22, 25, and 26, 1946, while the drugs were being held for sale after shipment in interstate commerce, the defendant removed portions of the drugs from the bottles and boxes in which they had been shipped, repacked them in boxes, and sold them to various persons without a prescription, which acts of the defendant resulted in the drugs being misbranded. The repackaged *sulfathiazole tablets* were labeled "Sulfathiazole"; the repackaged *thyroid tablets* were labeled in part "1 before meal twice daily Ellis Drug Store"; the repackaged *seconal pulvules* were labeled in part "(1) at Bed time Ellis Drug Store"; and the repackaged *nembutal capsules* were labeled in part "Nembutal 1 Evening upon retiring."

NATURE OF CHARGE: Misbranding, Section 502 (d), the *seconal pulvules* and the *nembutal capsules* were drugs for use by man and contained a chemical derivative of barbituric acid, which derivative had been found, by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as habit-forming, and the labels of the repackaged drugs failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith, the statement "Warning – May be habit-forming."

Misbranding, Section 502 (e) (2), the *thyroid tablets* were fabricated from 2 or more ingredients, and the label of the repackaged tablets failed to bear the common or usual name of each active ingredient, including the name and quantity or proportion of thyroid contained therein.

Misbranding, Section 502 (f) (1), the labeling of the *sulfathiazole tablets* and the *thyroid tablets* and the *nembutal capsules* was inadequate, since the repackaged *sulfathiazole tablets* bore no labeling containing directions for use, and since the directions "1 before meals twice daily" and "1 Evening upon retiring" on the boxes of the *thyroid tablets* and the *nembutal capsules*, respectively, were not adequate directions for use.

Misbranding, Section 502 (f) (2), the repackaged *sulfathiazole tablets* and the *thyroid tablets* and the *nembutal capsules* bore no labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health and against unsafe dosage and methods and duration of administration.

Misbranding, Section 502 (j), the repackaged *thyroid tablets* were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling thereof, "1 before meal twice daily."

DISPOSITION: June 4, 1947. A plea of guilty having been entered, the court imposed a fine of $50 on each of the 4 counts of the information.

2252. Misbranding of Brown's Neuritis Capsules. U. S. v. Randal J. Brown (Thomas A. Brown Pharmacy). Plea of nolo contendere. Defendant fined $200 and placed on probation for 1 year. (F. D. C. No. 21435. Sample Nos. 5433–H, 5439–H, 5440–H.)

INFORMATION FILED: December 13, 1946, District of New Jersey, against Randal J. Brown, trading as the Thomas A. Brown Pharmacy, Trenton, N. J.

ALLEGED SHIPMENT: On or about January 24 and February 19 and 20, 1946, from the State of New Jersey into the States of Delaware and Pennsylvania.

PRODUCT: Analyses disclosed that the product was a gelatin capsule containing a mixture of about 5 grains of cinchophen, with acetophenetidin, caffeine, emodin bearing drugs, and other materials.

NATURE OF CHARGE: Misbranding, Section 502 (a), the name of the article *Neuritis Capsules* was false and misleading, since it represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of neuritis, whereas the article would not be efficacious for such purposes; Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents, in that the bottle containing the article bore no label containing a statement of the quantity of the contents; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from 2 or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, in that the article, by reason of the